

REMARKS

In the Office Action dated July 29, 2004, Claims 1-10, 12, 14, 15 and 20-24 are pending and under consideration on the merits. The specification has been objected to as allegedly failing to provide proper antecedent basis for the claimed subject matter as recited in Claim 20. The specification has been objected to for certain informalities. Claims 1-10, 12, 14-15 and 20-24 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking descriptive support. Claim 20 has been rejected under 35 U.S.C. 102(b) as allegedly anticipated by Locarnini et al. (*Hepatology*, Vol. 27, 1998, pp. 294-297). Claim 20 has been rejected under 35 U.S.C. 112, second paragraph, as allegedly vague and confusing. Claims 21-24 have been rejected under 35 U.S.C. 112, second paragraph, as allegedly indefinite.

This Response addresses each of the Examiner's rejections and objections. Applicants therefore respectfully submit that the present application is in condition for allowance. Favorable consideration of all pending claims is therefore respectfully requested.

The specification has been objected to as allegedly failing to provide proper antecedent basis for the claimed subject matter as recited in Claim 20. In an effort to favorably advance the prosecution, Applicants have canceled Claim 20, without prejudice. Applicants reserve the right to file a continuing application directed to the subject matter in Claim 20. Accordingly, Applicants respectfully submit that the objection to Claim 20 is obviated and withdrawal thereof is respectfully requested.

The specification has been objected to for certain informalities. Specifically, the Examiner states that an amino acid sequence on page 2, line 5 of the specification is not

identified by SEQ ID NO. or portion of SEQ ID NO. The Examiner also states that the nucleotide sequences presented in Figures 3, 5 and 14 are not identified by SEQ ID NOs.

In response, Applicants have amended the specification on page 2, line 5 to recite the portion of SEQ ID NO: 8. Support for the amendment can be found on page 17, line 18 to page 19, line 24 and Figure 2. Applicants have also amended the descriptions for Figures 3, 5 and 14 to identify the recited sequences in each figure by SEQ ID NOs. Support for the amendment of Figures 3, 5 and 14 can be found in original descriptions of Figures 3 and 5 and SEQ ID NOs 9-22. No new matter is introduced.

Accordingly, Applicants respectfully submit that the specification, as amended, is in compliance with the requirement as set forth in 37 CFR 1.821 to 1.825. Therefore, the objection to the Sequence Listing formalities is obviated and withdrawal thereof is respectfully requested.

Claims 1-10, 12, 14-15 and 21-24 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking descriptive support.

Specifically, the Examiner alleges that Applicants introduced new matter in the response to the previous Official Action by amending Claims 1, 23 and 24 to recite cells of "hepatic origin." The Examiner takes the position that cells of hepatic origin can encompass all cell types of hepatic origin to include oval cells, sinusoidal epithelial cells and hepatic stem cells.

Applicants observe that the Examiner acknowledges that the present application provides adequate descriptive support for cell lines of HepG2 and Huh7 and any hepatocyte cell line or primary hepatocyte cell culture. Applicants also note that the Examiner appears to be of the opinion that the present invention contemplates hepatocyte cells. In an effort to favorably advance the prosecution, Applicants have amended Claims 1, 23 and 24 to recite "hepatocyte cells." Support for the amendments can be found throughout the specification, e.g., on page 36,

lines 1-4. Accordingly, Applicants respectfully submit that the present application provides adequate descriptive support for Claims 1-10, 12, 14-15 and 20-24. Withdrawal of the rejection of Claims 1-10, 12, 14-15 and 21-24 under 35 U.S.C. §112 first paragraph, is respectfully requested.

Claim 20 has been rejected under 35 U.S.C. 102(b) as allegedly anticipated by Locarnini et al. and under 35 U.S.C. 102(a) as allegedly anticipated by Oon et al. Claim 20 has also been rejected under 35 U.S.C. 112, first paragraph, as allegedly lacking descriptive support. Claim 20 has further been rejected under 35 U.S.C. 112, second paragraph, as allegedly indefinite.

As submitted above, Claim 20 has been canceled, without prejudice. Accordingly, the above rejections of Claim 20 are moot.

Claims 21-24 have been rejected under 35 U.S.C. 112, second paragraph, as allegedly indefinite.

The Examiner alleges that Claims 21 and 22 are vague in the recitation "the variant HBV." The Examiner suggests that the claims should recite "different variant HBV." The Examiner also alleges that Claim 21 is vague by reciting the phrase "multiple combinations of the variant HBV comprises." The Examiner states that the term "comprises" in the phrase should be "comprising." The Examiner alleges that Claim 23 is vague by reciting a method for detecting a variant HBV without reciting a step or steps which would detect the variant with the recited DNA polymerase. The Examiner also alleges that Claim 24 is vague because it is unclear as to which HBV the phrase "the HBV" in line 11 refers.

In response, Applicants have amended Claims 21-22 to recite "different variant HBV," in accordance with the Examiner's suggestion. Applicants have also amended Claim 23

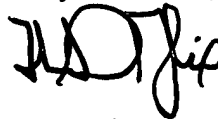
to recite a step for detecting the variant with the recited DNA polymerase. Applicants have clarified Claim 24 by reciting "said variant HBV" instead of "the HBV." Support for the amendment of Claims 21-24 can be found in the specification, on page 7, line 23 to page 8, line 2, page 38, line 13 to page 39, line 27 and original Claims 23-24, for example. In addition, Applicants have also replaced the phrase "multiple combinations of the variant HBV comprises" with "multiple combinations of the variant HBV comprising" in Claim 21 for grammatical consistency.

Accordingly, the rejection of Claims 21-24 under 35 U.S.C. 112, second paragraph, is overcome and withdrawal thereof is respectfully requested.

The Examiner indicates that the term "HBV" is misspelled as "HBB" in Claim 9. In response, Applicants have made the correction as required by the Examiner. The Examiner also requires that the Figure descriptions should be numbered consecutively. In response, Applicants respectfully submit that the Figure descriptions, as amended, are numbered consecutively.

In view of the foregoing amendments and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,



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